

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of smart phone self-care application on quality of life in patients with liver cirrhosis

#### Protocol summary

##### Study aim

Comparison of the Effect of face to face training and self-care software under smart phones on the quality of life of patients with liver cirrhosis

##### Design

In this research, 60 eligible patients with liver cirrhosis, referring to Imam Reza and Ghaem hospitals were chosen purposefully and a code was allocated to each one of them. Then, patients in a minimization method were divided into two control and software groups.

##### Settings and conduct

The study is done in two parts. The first part is the provision of the content of the software and its production. In the second part, 60 patients with liver cirrhosis referring to Ghaem Hospital and Imam Reza Hospital and specialized liver clinics in Mashhad were selected according to entry criteria and divided into two groups. the patients in the software group will have a 45-minute individual training session on how to install the software and work with it, and for the control group, there are two 45-minute face-to-face sessions. Both groups are followed up for a month. Quality of life questionnaire before the intervention, two weeks and four weeks after the intervention, will be completed in two groups and at the end of the data analysis will be done.

##### Participants/Inclusion and exclusion criteria

Participants must have ages 20-65 years, access to Android smartphone, and have the skills to use it, AND not participate in the previous self-care program, and not be candidates for the Transplant. If the patient has such cases as death, candidation for transplantation or exacerbation of the disease, will be excluded FROM the study .

##### Intervention groups

Intervention on liver cirrhosis patients admitted to the hospital or referring to the office which has entry criteria, will begin with available sampling method and random allocation will be made to the software and comparison

groups. the patients in the software group will have a individual training session on how to install the software and work with it, and will give them a booklet on how to use the software. The comparison group will receive the equivalent educational content in two session in face-to-face manner, and during the training, a question and answer will be made between the researcher and the patient, as needed. further information will be provided as a pamphlet to the patient. Patients are followed up by researcher, as a weekly phone call for a period of one month.

##### Main outcome variables

Quality of Life

#### General information

##### Reason for update

##### Acronym

does not have

##### IRCT registration information

IRCT registration number: **IRCT20171030037098N1**

Registration date: **2017-11-22, 1396/09/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-11-22, 1396/09/01**

Update count: **0**

##### Registration date

2017-11-22, 1396/09/01

##### Registrant information

##### Name

علیه ولی زاده

##### Name of organization / entity

دانشگاه علوم پزشکی مشهد

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3723 6287

##### Email address

valizadeha941@mums.ac.ir

**Recruitment status****Recruitment complete****Funding source****Expected recruitment start date**

2017-11-11, 1396/08/20

**Expected recruitment end date**

2018-01-10, 1396/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of smart phone self-care application on quality of life in patients with liver cirrhosis

**Public title**

Effect of self care program on liver cirrhosis quality of life

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient has definitive diagnosis of cirrhosis of the liver in steps A and B of the Childe classification. Aged 20-65. Has not participated in the previous or current self-care program. Access to Android smartphone. The use of the smartphone literacy Patient is not a candidate for a transplant.

**Exclusion criteria:**

The patient's death occurs. The patient should be bonded during the research.

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, the minimization method is used. In which patients were examined for three characteristics of age, gender and economic status, one person in the control group and one in the software group from both the same person.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is one-way blind. In this study, patients without knowing what they are supposed to be and in what group are randomly divided into two groups and that they are not known to be in the control group or

intervention.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Quraishi Building, University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91375345

**Approval date**

2017-10-07, 1396/07/15

**Ethics committee reference number**

IR.MUMS.REC.1396.190

**Health conditions studied****1****Description of health condition studied**

Cirrhosis of the liver

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Quality of Life

**Timepoint**

Zero, two weeks, one month

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Provide educational software under

the Android operating system and provide it to the patient

**Category**  
Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Imam Reza Hospital

**Full name of responsible person**  
aliyyeh vali zadeh

**Street address**  
daneshgah

**City**  
mashhad

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Razavi Khorasan

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9184911111

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+98 51 3802 2000

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valizadeha941@mums.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**  
Ghaem Hospital

**Full name of responsible person**  
aliyyeh vali zadeh

**Street address**  
Ahmad abad

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Dr. Robab Latifnezhad

**Street address**  
University Street, Dr. Crossroads, Ibn Sina St

**City**  
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9137913199

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valizadeha941@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Mashhad University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
empty

**Country of origin**

**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Aliyyeh Vali zadeh

**Position**  
Masters student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

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Faculty of Nursing and Midwifery, Ibn Sina Avenue, Doctor's Crossroads, University Street

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## Person responsible for scientific inquiries

#### Contact

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Vali zadeh, Aliyyeh

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Masters student

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## Person responsible for updating data

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**Other areas of specialty/work**  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Undecided - It is not yet known if there will be a plan to make this available  
**Data Dictionary**  
Not applicable